UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 11 2002

MEMORANDUM

SUBJECT: Amended Registration of R-ST SM (EPA File Symbol No.074032-1) Containing 95.5% S-Methoprene: Chemical No. 105401; Case No. 068819; Review of Eco-toxicity . Submission No. S607641; MRID Nos. 455434-01,-02, -03, -05 and Data Waiver Request ; DP Barcode No. D279871

FROM: Freshteh Toghrol, Ph.D., Senior Scientist F. Toghrol
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division

TO: Jim Downing, Team Leader
Biochmical Pesticides Branch
Biopesticides & Pollution Prevention Division

ACTION REQUESTED

Hartz-B2E LLC, requests amended registration of R-ST SM (EPA File Symbol No.074032-1) containing 95.5% S-Methoprene..

To support this amended registration, the registrant has submitted the following studies: an avian acute oral toxicity test (MRID No. 455434-01), an avian dietary toxicity test (MRID No. 455434-02), a fish acute toxicity test, on freshwater and marine (MRID No. 455434-03), and an aquatic invertebrate acute toxicity test, on freshwater daphnia (MRID No.455434-04).

BPPD'S CONCLUSIONS AND RECOMMENDATIONS

Submitted eco-toxicity studies are acceptable, but the label amendment is not acceptable. The label language for manufacturing-use product (MP) is standard language, which insures that a formulator who purchases this technical grade active ingredient (TGAI) **must submit the appropriate data to the Agency for registration of his/her end-use product**. Therefore this language can not be removed from the label.

STUDY SUMMARIES

154-6 Acute Oral Toxicity in Bobwhite (MRID 455434-01)

Fifteen male and 15 females northern bobwhite (Colinus virginianus) were administered the test material in corn oil by oral gavage at a single dose of 24.7 mg a.i./kg body weight. Five males and 5 females comprised the control group and were administered corn oil without R-ST SM. Food was withheld for 24 hours prior to dosing. Birds were weighed on the test day (day 0) and on test days 3, 7, and 14. Feed consumption (Nutrena Gamebird breeder) was also measured on these days. The test animals were observed for clinical signs and mortality frequently on the day of dosing and at least daily thereafter for 14 days. No mortality was observed in the 30 northern bobwhite exposed to 24.7 mg a.i./kg body weight of R-ST SM. No mortality was observed in the 10 birds in the control. No test substance related signs of sublethal toxicity were observed in any of the test birds. Body weights of the test birds were compared to vehicle control birds and were analyzed using ANOVA. Gross pathological examinations were conducted on 8 birds (4 control and 4 treated) euthanized at termination of the definitive test. No test substance related abnormalities or other indications of toxicity were noted during the examinations. The 14-day acute oral LD_{50} was greater than 24.7 mg a.i/kg body weight. The 14-day NOEL of R-ST SM to the northern bobwhite was 24.7 mg a.i/kg body weight. The study is acceptable.

154 -7 Dietary Toxicity Test in Bobwhite (MRID 455434-02)

The toxicity of R-ST SM was assessed in 17-day old northern bobwhite (*Colinus virginianus*) via the diet. The definitive test consisted of exposing 10 birds (5 males and 5 females) to each test concentration administered via the diet (Turkey and Gamebird starter) at measured concentrations of 0, 8, 13, 22, 37, and 62 mg a.i./kg diet. Fifteen males and 15 females comprised the vehicle control group which were administered feed without R-ST SM but with the vehicle control acetone. Fresh diets were provided each day for the five day test and birds were allowed *ad libitum* access to feed and water. Birds were weighed on the test day (day 0) and on days 5 and 8. Eight days after test initiation, 4 untreated birds and 20 treated birds (4 from each test concentration) were selected, sacrificed by asphyxiation, and examined for gross pathological changes of the major organs. No toxicological symptoms were noted in any of the test birds during the 5-day diet treatment or the 3-day recovery period. No sublethal toxic effects where observed in birds based upon analyses of feed consumption, body weight, and gross pathological examination conducted at study termination. The NOEC was determined to be 62 mg a.i./kg diet. The acute LC_{50} was >62 mg a.i/kg diet.. The study is acceptable

154-8 Fish Acute Toxicity Test, Freshwater and Marine (MRID 455434-03

In an acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to R-ST SM at nominal concentrations of 0.31, 0.63, 1.3, 2.5, 5.0 and 100 mg a.i./L. Mean measured concentrations of R-ST SM in static test solutions were 0.128, 0.316, 0.622, 1.98, 3.04, and 31.5 mg a.i./L. The test organism was rainbow trout (*Oncorhynchus mykiss)* impartially assigned to 5 treatment groups, a negative control and a vehicle control group based on results of a range finding study. Each group consisted of 10 rainbow trout from the same source and year class. Test chambers were 20-L glass aquaria with 15 L of test solution prepared for static conditions. Oxygen content (>82% saturation), pH (7.44-8.49), and temperature (11.2-12.2°C) were measured throughout the 96-hour test. Observations of mobility and clinical signs of toxicity were made at 0, 24, 48, 72, and 92 hours of

the test. No mortality was observed in the rainbow trout after 96 hours of exposure to R-ST SM under static test conditions. Sublethal toxic effects were observed after 24 hours of exposure in the ≥0.622 mg a.i./L test solutions. Observed effects in the trout were darkened color, irregular respiration, and loss of equilibrium. No sublethal toxic effects were noted in the ≤0.316 mg a.i./L test solutions and the controls. Based on mean measured concentrations of R-ST SM, the 96 hour LC_{50} value for rainbow trout was >31.5 mg a.i./L. The 96 hour NOEC was 0.316 mg a.i./L based on an absence of sublethal effects at this and lower concentrations. The study is acceptable.

154-9 Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids

Test organisms were neonate cladocerans (*Daphnia magna)* which were not more than 24 hours old at the beginning of the tests. Two replicates (10 daphnids per replicate) were tested for each treatment and control group for a total of 20 daphnids in each group. Initial range finding studies determined treatment concentrations for the definitive study. In the definitive study, daphnids were exposed to five R-ST SM nominal test concentrations of 0.063, 0.13, 0.25, 0.50, and 1.0. Mean measured test concentrations in static solutions were 0.0431, 0.084, 0.208, 0.334, and 0.642. Test chambers were glass beakers containing 200 mL of dilution water. Immobility and sublethal effects were observed after 24 and 48 hours of exposure in the 0.084 mg a.i./L and greater test solutions. The 48-hour EC_{50} was 0.084 mg a.i./L (95% confidence limit 0.070 and 0.098 mg a.i./L). The 48-hour NOEC was 0.0431 mg a.i./L. The study is acceptable.

DATA EVALUATION RECORD

R-ST SM (S-METHOPRENE)

STUDY TYPE: Avian Acute Oral Toxicity Test (850.2100)
MRID 45543401

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No.107

Primary Reviewer:
Anthony Q. Armstrong, M.S.

Signature: _____
Date: FEB 14 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: _____
Date: FEB 14 2002

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: FEB 14 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: FEB 14 2002

Disclaimer

This record may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725.

DATA EVALUATION RECORD

Reviewed by: **Freshteh Toghrol, Ph.D.**

Secondary Reviewer: **Freshteh Toghrol, Ph.D.** F. Toghrol 3/6/02

STUDY TYPE:	Avian Acute Oral Toxicity Test (OPPTS 850.2100)
MRID NO.:	45543401
TEST MATERIAL:	R-ST SM (S-Methoprene)
STUDY NO.:	Genesis Laboratories Inc.: 01008
SPONSOR/SUBMITTER:	B2E Corporation, 500 Mamaroneck Ave., Harrison, NY 10528
TESTING FACILITY:	Genesis Laboratories, Inc., 10122 N.E. Frontage Road, Wellington, CO 80549
TITLE OF ARTICLE:	Avian Single-Dose Oral Limit Test With R-ST SM [S-Methoprene
AUTHOR(S):	Jeff J. Mach, Robert R. Troup
PUBLICATION:	October 9, 2001
CONFIDENTIALITY CLAIMS:	None
STUDY SUMMARY:	The acute oral toxicity of R-ST SM to 18-week old northern bobwhite (*Colinus virginianus*) was assessed over 14 days. R-ST SM was administered to the birds by oral gavage at 24.7 mg a.i./kg body weight. The 14-day acute oral LD_{50} was >24.7 mg a.i/kg body weight. The 14-day NOEL of R-ST SM to the northern bobwhite, was 24.7 mg a.i/kg body weight. No toxic effects where observed in birds based upon analyses of feed consumption, loss of body weight, and gross pathological examination conducted at study termination.
CLASSIFICATION:	Acceptable; meets toxicity testing requirements.
GOOD LABORATORY PRACTICE:	EPA GLP statement, signed and dated

Test material: R-ST SM [S-Methoprene] was provided as clear-amber liquid. The lot number was OP.1S/01 and purity was 97.7% as stated by the study sponsor. R-ST SM was stable in liquid form with water or organic solvents. R-ST SM was stored at room temperature in the cool and dry

Test methods: Test organism was the northern bobwhite (*Colinus virginianus*) supplied by the Barrett's Quail Farm, Houston, TX. The birds, of apparent good health, were held in acclimation for 14 days prior to testing. Age at testing was 18-weeks old and the weights were between 238 and 290 grams. No range-finding test was conducted. The definitive test consisted of a limit test in which 15 males and 15 females were administered the test material in corn oil by oral gavage at a single dose of 24.7 mg a.i./kg body weight. Five males and 5 females comprised the control group and were administered corn oil without R-ST SM. Food was withheld for 24 hours prior to dosing. Birds were weighed on the test day (day 0) and on test days 3, 7, and 14. Feed

consumption (Nutrena Gamebird breeder) was also measured on these days. Tap water was provided *ad libitum*. Birds were observed twice daily for clinical signs, mortality, and moribundity during the 14-day observation period. Birds were housed in plastic coated wire pens 51 cm (l) × 25 cm (w) × 25.5 cm (h) with a floor surface area of 1275 sq. cm. Temperature and humidity were monitored and ranged between 22 and 29°C and 36 and 62%, respectively; illumination was 10 hours/day. Fourteen days after test initiation, 4 untreated birds and 4 treated birds were selected, sacrificed by asphyxiation, and examined for gross pathological changes of the major organs.

Results summary: No mortality was observed in the 30 northern bobwhite exposed to 24.7 mg a.i./kg body weight of R-ST SM. No mortality was observed in the 10 birds in the control.

No test substance related signs of sublethal toxicity were observed in any of the test birds. Body weights of the test birds were compared to vehicle control birds and were analyzed using ANOVA. Differences in mean body weights were not significant (p=0.05) throughout the 14 day study period. Mean feed consumption per bird was determined and analyzed using one-way ANOVA and Dunnett's t-test. No significant differences (p=0.05) in feed consumption among groups were found for days 7-14. Gross pathological examinations were conducted on 8 birds (4 control and 4 treated) euthanized at termination of the definitive test. No test substance related abnormalities or other indications of toxicity were noted during the examinations.

Study author's conclusions: R-ST SM was orally administered to 18-week old northern bobwhite (*Colinus virginianus*) at 0 and 24.7 mg a.i./kg body weight. No toxicological symptoms were noted in any of the test birds during the 14-day observation period. The 14-day acute oral LD_{50} was greater than 24.7 mg a.i/kg body weight. The 14-day NOEL of R-ST SM to the northern bobwhite was 24.7 mg a.i./kg body weight.

Reviewer's conclusion: The study followed OPPTS 850.2100 guidelines, standard laboratory procedures, and is acceptable. We agree with the study author's conclusions stated above.

DATA EVALUATION RECORD

R-ST SM (S-METHOPRENE)

STUDY TYPE: Avian Dietary Toxicity Test (850.2200)
MRID 45543402

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No.107

Primary Reviewer:
Anthony Q. Armstrong, M.S.

Signature: Anthony Q. Armstrong
Date: Feb 14, 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: Patricia H. Reno
Date: February 14, 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: 14 Feb 14, 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: Feb 14, 2002

Disclaimer

This record may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725.

MRID No. 45543402

DATA EVALUATION RECORD

Reviewed by: Freshteh Toghrol, Ph.D.

Secondary Reviewer: Freshteh Toghrol, Ph.D. F. Toghrol **3/6/02**

STUDY TYPE:	Avian Dietary Toxicity Test (OPPTS 850.2200)
MRID NO.:	45543402
TEST MATERIAL:	R-ST SM (S-Methoprene)
STUDY NO.:	Genesis Laboratories Inc.: 01009
SPONSOR/SUBMITTER:	B2E Corporation, 500 Mamaroneck Ave., Harrison, NY 10528
TESTING FACILITY:	Genesis Laboratories, Inc., 10122 N.E. Frontage Road, Wellington, CO 80549
TITLE OF ARTICLE:	Avian Dietary LC_{50} Test With R-ST SM [S-Methoprene TGAI] in Northern Bobwhite (*Colinus virginianus*)
AUTHOR(S):	Robert R. Troup, Jeff J. Mach
PUBLICATION:	October 23, 2001
CONFIDENTIALITY CLAIMS:	None
STUDY SUMMARY:	The toxicity of R-ST SM was assessed in 17-day old northern bobwhite (*Colinus virginianus*) via the diet. R-ST SM was administered to the birds at 0, 8, 13, 22, 37, and 62 mg a.i./kg diet. No toxicological symptoms were noted in any of the test birds during the 5-day diet treatment or the 3-day recovery period. The NOEC was determined to be 62 mg a.i./kg diet. The acute LC_{50} was >62 mg a.i/kg diet. No toxic effects were observed in birds based upon analyses of feed consumption, loss of body weight, and gross pathological examination conducted at study termination.
CLASSIFICATION:	Acceptable; meets toxicity testing requirements.
GOOD LABORATORY PRACTICE:	EPA GLP statement, signed and dated

Test material: R-ST SM [S-Methoprene] was provided as clear-amber liquid. The lot number was OP.1S/01 and purity was 97.7% as stated by the study sponsor. R-ST SM was stable in liquid form with water or organic solvents. R-ST SM was stored at room temperature in the cool and dry.

Test methods: Test organism was the northern bobwhite (*Colinus virginianus*) supplied by Sand Prairie Quail Farm, Maquoketa, Iowa. The birds, of apparent good health, were held in acclimation for 16 days prior to testing. Age at testing was 17-days old and the weights were between 20 and 30 grams. No range-finding test was conducted. The definitive test consisted of exposing 10 birds (5 males and 5 females) to each test concentration administered via the diet

(Turkey and Gamebird starter) at measured concentrations of 0, 8, 13, 22, 37, and 62 mg a.i./kg diet. Fifteen males and 15 females comprised the vehicle control group which were administered feed without R-ST SM but with the vehicle control acetone. Fresh diets were provided each day for the five day test and birds were allowed *ad libitum* access to feed and water. Birds were weighed on the test day (day 0) and on days 5 and 8. Feed consumption was also measured on these days. Birds were observed twice daily for clinical signs, mortality, and moribundity during the 8-day testing period. Birds were housed in steel brooders 90 cm (l) x 80 cm (w) x 25 cm (h) with a floor surface area of 7200 sq. cm. Brooder temperature ranged between 36 and 40°C and 36 and 62% and illumination was 12 hours/day. Eight days after test initiation, 4 untreated birds and 20 treated birds (4 from each test concentration) were selected, sacrificed by asphyxiation, and examined for gross pathological changes of the major organs.

Results summary: No mortality was observed in the northern bobwhite exposed to 8, 13, 22, 37, and 62 mg a.i./kg diet of R-ST SM. No mortality was observed in the vehicle controls.

No test substance-related signs of sublethal toxicity were observed in any of the test birds. Body weights of the test birds were compared to vehicle control birds and were analyzed using Toxstat 3.4 and ANOVA. Differences in mean body weights were not significant (p=0.05) at day 0,5, and 8 of the study. Visual review of the feed consumption per bird data indicates consistent rates of consumption throughout the 8 days of the study. Gross pathological examinations were conducted on 24 birds (4 control and 4 from each treatment group) euthanized at termination of the definitive test. No test substance-related abnormalities or other indications of toxicity were noted during the examinations.

Study author's conclusions: The toxicity of R-ST SM was assessed in 17-day old northern bobwhite (*Colinus virginianus*) via the diet. R-ST SM was administered to the birds at 8, 13, 22, 37, and 62 mg a.i./kg diet. No toxicological symptoms were noted in any of the test birds during the 5-day diet treatment or the 3-day recovery period. The NOEC was determined to be 62 mg a.i./kg diet. The LC_{50} was >62 mg a.i/kg diet.

No sublethal toxic effects where observed in birds based upon analyses of feed consumption, body weight, and gross pathological examination conducted at study termination.

Reviewer's conclusion: The study followed OPPTS 850.2200 guidelines, standard laboratory procedures, and is acceptable. We agree with the study author's conclusions stated above.

DATA EVALUATION RECORD

R-ST SM (S-METHOPRENE)

STUDY TYPE: Fish Acute Toxicity Test, Freshwater and Marine (850.1075)
MRID 45543403

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831

Task Order No.107

Primary Reviewer:
Anthony Q. Armstrong, M.S.

Signature: [signature]
Date: FEB 14 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: [signature]
Date: FEB 14 2002

Robert H. Ross, M.S., Group Leader

Signature: [signature]
Date: FEB 14 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: [signature]
Date: FEB 14 2002

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DATA EVALUATION RECORD

Reviewed by: **Freshteh Toghrol Ph.D.**

Secondary Reviewer: **Freshteh Toghrol Ph.D.** F. Toghrol 3/7/02

STUDY TYPE:	Fish Acute Toxicity Testing, Freshwater and Marine (OPPTS 850.1075)
MRID NO.:	45543403
TEST MATERIAL:	R-ST SM (S-Methoprene)
STUDY NO.:	ABC Study No. 46708
SPONSOR/SUBMITTER:	B2E Corporation, 500 Mamaroneck Ave., Harrison, NY 10528
TESTING FACILITY:	ABC Laboratories, Inc., 7200 E. ABC Lane, Columbia, Missouri 65202
TITLE OF ARTICLE:	Acute Toxicity of R-ST SM [S-Methoprene TGAI] to the Rainbow Trout, *Oncorhynchus mykiss*, Determined Under Static Test Conditions
AUTHOR(S):	Timothy Madsen
PUBLICATION:	October 19, 2001
CONFIDENTIALITY CLAIMS:	None
STUDY SUMMARY:	In an acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to R-ST SM at nominal concentrations of 0.31, 0.63, 1.3, 2.5, 5.0 and 100 mg a.i./L. Mean measured concentrations of R-ST SM in static test solutions were 0.128, 0.316, 0.622, 1.98, 3.04, and 31.5 mg a.i./L. No mortality was observed in the rainbow trout after 96 hours of exposure. Sublethal toxic effects were observed after 24 hours of exposure in the $\geq$0.622 mg a.i./L test solutions. Observed effects in the trout were darkened color, irregular respiration, and loss of equilibrium. No sublethal toxic effects were noted in the $\leq$0.316 mg a.i./L test solutions and the controls. Based on mean measured concentrations of R-ST SM, the 96 hour LC_{50} value for rainbow trout was >31.5 mg a.i./L. The 96 hour NOEC was 0.316 mg a.i./L based on an absence of sublethal effects at this and lower concentrations.
CLASSIFICATION:	Acceptable; meets toxicity testing requirements.
GOOD LABORATORY PRACTICE:	EPA GLP statement, signed and dated

Test material: R-ST SM [S-Methoprene] was provided as clear-amber liquid. The lot number was OP.1S/01 and purity was 97.7% as stated by the study sponsor. R-ST SM was stable in liquid form with water or organic solvents. R-ST SM was stored at room temperature in the cool and dry.

Test methods: The test organism was rainbow trout (*Oncorhynchus mykiss)* impartially assigned

to 5 treatment groups, a negative control and a vehicle control group based on results of a range finding study. Each group consisted of 10 rainbow trout from the same source and year class. The mean weight of the trout was 1.259 g (range 0.747 g to 1.792 g) and the mean length was 46 mm (range 39 mm to 52 mm). Nominal test concentrations for R-ST SM were 0.31, 0.63, 1.3, 2.5, 5.0, and 100 mg a.i./L. These concentrations correspond to mean measured concentrations of 0.128, 0.316, 0.622, 1.98, 3.04, and 31.5 mg a.i./L. Test concentrations were prepared by mixing the test substance directly with dilution water (well water, UV treated and aged) on a volume to volume basis. Test chambers were 20-L glass aquaria with 15 L of test solution prepared for static conditions. Oxygen content (>82% saturation), pH (7.44-8.49), and temperature (11.2-12.2°C) were measured throughout the 96-hour test. Water analyses of the test solutions and well water for hardness, alkalinity, specific conductance, pesticides, organics, metals, and other inorganics were normal and did not affect the tests. Photoperiods of 16 hours light and 8 hours darkness were also maintained during testing. Observations of mobility and clinical signs of toxicity were made at 0, 24, 48, 72, and 92 hours of the test.

Results summary: Mortality and sublethal results are summarized in Table 1. After 96 hours of exposure, mortality was 0% in all test solutions.

Sublethal toxic effects were observed in the rainbow trout after 24 hours exposure to R-ST SM in the three highest test solutions (1.98, 3.04, 31.5 mg a.i./L). Observations noted included dark colored trout, irregular respiration, and loss of equilibrium (Table 1). After 48 hours exposure, toxic effects were noted in the 0.622, 1.98, 3.04, and 31.5 mg a.i./L test solutions. Sublethal toxic effects were noted repeatedly in these test solutions until study termination at 96 hours.

Study Author's Conclusions

No mortality was observed in the rainbow trout after 96 hours of exposure to R-ST SM under static test conditions. Sublethal toxic effects were observed after 24 hours of exposure in the $\geq$0.622 mg a.i./L test solutions. Observed effects in the trout were darkened color, irregular respiration, and loss of equilibrium. No sublethal toxic effects were noted in the $\leq$0.316 mg a.i./L test solutions and the controls. Based on mean measured concentrations of R-ST SM, the 96 hour LC_{50} value for rainbow trout was >31.5 mg a.i./L. The 96 hour NOEC was 0.316 mg a.i./L based on an absence of sublethal effects at this and lower concentrations.

Reviewer's Conclusion

The study followed OPPTS 850.1075 guidelines, standard laboratory procedures, and is acceptable. We concur with the study author's conclusions stated above.

TABLE 1. Summary of cumulative percent mortality and sublethal related effects in rainbow trout (*Oncorhynchus mykiss*) exposed to R-ST SM for 96 hours under static conditions.

Mean Measured Conc. (mg a.i./L)	24-hours		48-hours		72-hours		96-hours	
	% Mortality	Effects[1]	% Mortality	Effects	% Mortality	Effects	% Mortality	Effects
0 (no-dose control)	0	0	0	0	0	0	0	0
0 (vehicle control)	0	0	0	0	0	0	0	0
0.128	0	0	0	0	0	0	0	0
0.316	0	0	0	0	0	0	0	0
0.622	0	0	0	3	0	2	0	2
1.98	0	10	0	10	0	10	0	10
3.04	0	11	0	11	0	12	0	14
31.5	0	10	0	10	0	12	0	16

[1] Sublethal affects observed in trout were darkened pigmentation, irregular respiration, and/or loss of equilibrium. The number indicates the number of trout out of 20 that exhibited sublethal effects.

DATA EVALUATION RECORD

R-ST SM (S-METHOPRENE)

STUDY TYPE: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids (850.1010)
MRID 45543404

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No.107

Primary Reviewer:
Anthony Q. Armstrong, M.S.

Signature: _____
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Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: _____
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Robert H. Ross, M.S., Group Leader

Signature: _____
Date: FEB 14 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725.

DATA EVALUATION RECORD

Reviewed by: Freshteh Toghrol Ph.D.

Secondary Reviewer: Freshteh Toghrol Ph.D. F. Toghrol 3/7/02

STUDY TYPE:	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids, (OPPTS 850.1010)
MRID NO.:	45543404
TEST MATERIAL:	R-ST SM (S-Methoprene)
STUDY NO.:	ABC Study No. 46709
SPONSOR/SUBMITTER:	B2E Corporation, 500 Mamaroneck Ave., Harrison, NY 10528
TESTING FACILITY:	ABC Laboratories, Inc., 7200 E. ABC Lane, Columbia, Missouri 65202
TITLE OF ARTICLE:	Acute Toxicity of R-ST SM [S-Methoprene TGAI] to the Water Flea, *Daphnia magna*, Determined Under Static Test Conditions
AUTHOR(S):	Timothy Madsen
PUBLICATION:	October 19, 2001
CONFIDENTIALITY CLAIMS:	None
STUDY SUMMARY:	In an acute toxicity study, *Daphnia magna* were exposed to R-ST SM at nominal concentrations of 0, 0.063, 0.13, 0.25, 0.50, and 1.0 mg a.i./L. Mean measured concentrations of R-ST SM in static test solutions were 0.0431, 0.084, 0.208, 0.334, and 0.642 mg a.i./L. Immobility and sublethal effects were observed after 24 and 48 hours of exposure in the 0.084 mg a.i./L and greater test solutions. The 48-hour EC_{50} was 0.084 mg a.i./L (95% confidence limit 0.070 and 0.098 mg a.i./L). The 48-hour NOEC was 0.0431 mg a.i./L.
CLASSIFICATION:	Acceptable
GOOD LABORATORY PRACTICE:	EPA GLP statement was signed and provided.

Test material: R-ST SM [S-Methoprene] was provided as clear-amber liquid. The lot number was OP.1S/01 and purity was 97.7% as stated by the study sponsor. R-ST SM was stable in liquid form with water or organic solvents. R-ST SM was stored at room temperature in the cool and dry.

Test methods. Test organisms were neonate cladocerans (*Daphnia magna)* which were not more than 24 hours old at the beginning of the tests. Two replicates (10 daphnids per replicate) were tested for each treatment and control group for a total of 20 daphnids in each group. Initial range finding studies determined treatment concentrations for the definitive study. In the definitive study, daphnids were exposed to five R-ST SM nominal test concentrations of 0.063, 0.13, 0.25, 0.50, and 1.0. Mean measured test concentrations in static solutions were 0.0431, 0.084, 0.208, 0.334, and 0.642. Test chambers were glass beakers containing 200 mL of dilution water.

Dilution water was filtered well water, UV treated and aged prior to use. Water analyses of the dilution water for hardness, alkalinity, specific conductance, pesticides, organics, metals, and other inorganics were normal and did not affect the tests. Oxygen content (.93% saturation), pH (7.85-8.23), and temperature (19.9-20.1°C) were measured throughout the 48 hour test. Photoperiods of 16 hours light and 8 hours darkness were maintained during testing. Observations of mortality, immobility, and sublethal effects were made at 24 and 48 hours.

Results summary: Immobilization/mortality results are summarized in Table 1. After 48 hours of exposure, immobility/mortality was 0, 60, 100, 100, and 100% in the 0.0431, 0.084, 0.208, 0.334, and 0.642 mg a.i./L mean measured treatment groups, respectively.

Data on immobility includes sublethal effects noted during observations after 24 and 48 hours of exposure. Several daphnids were identified as quiescent after 24 hours exposure in the 0.334 and 0.642 test solutions.

24 and 48 hour EC_{50} values and corresponding 95% confidence limits were calculated using the Trimmed Spearman-Karber procedure. The slope of the 48 hour dose-response curve was calculated by a probit analysis computer program. The NOEC was derived by direct inspection of the data on the immobility of the daphnids.

TABLE 1. Effect of R-ST SM on immobility/mortality of *Daphnia magna*.

Treatment Levels (mean measured concentration, mg a.i./L)	No. of organisms	Observation period			
		24-hours		48-hours	
		No Dead	% Immobility	No Dead	% Immobility
0 (no-dose control)	20	0	0	0	0
0 (vehicle control	20	0	0	0	0
0.0431	20	0	0	0	0
0.084	20	7	35	12	60
0.208	20	20	100	20	100
0.334	20	15	75	20	100
0.642	20	17	85	20	100

Study author's conclusions: Under the conditions of this study, the 48 hour EC_{50} for *Daphnia magna* exposed to R-ST SM [S-Methoprene] was 0.084 mg a.i./L with 95% confidence limits of 0.070 and 0.098 mg a.i./L. The 48-hour NOEC was 0.0431 mg a.i./L based on the absence of immobility/mortality and sublethal effects at this test concentration (the lowest R-ST SM concentration tested).

Reviewer's conclusion: The study followed OPPTS 850.1010 guidelines, standard laboratory procedures, and is acceptable. We concur with the study author's conclusions stated above.

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Chemical: Methoprene

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105401

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